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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,078

02/07/2006

Leslie Philip Miranda

0944-UTL-GY

4061

44638 7590 01/22/2010

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EXAMINER

HEARD, THOMAS SWEENEY

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

01/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/541,078
Filing Date: February 07, 2006
Appellant(s): MIRANDA ET AL.

Richard San Pietro Registration No. 45,071
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 8th, 2009 appealing from the Office action mailed April 13th, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

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(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 60-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

"To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and

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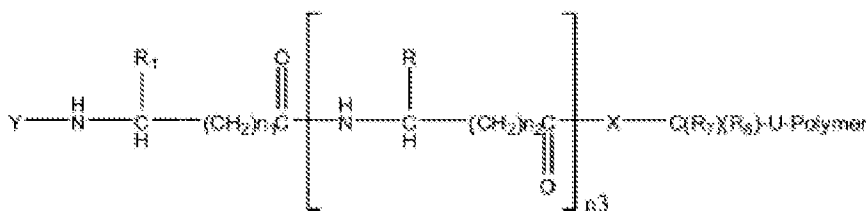
function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention.

In the instant case, the claims are drawn to compounds of the formula:



R and R₁ are individually selected from the group consisting of: hydrogen, a side chain of an amino acid, a branched alkane, a cycloalkane, an alkyl-substituted aryl or heteroaryl group, and combinations thereof;

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R_7 and R_8 are each, individually, selected from hydrogen, substituted and unsubstituted linear or branched chain alkyl, aryl, heteroaryl and benzyl;

U is a linker or spacer and may be present or absent and, when present consists of a linear or branched chain alkyl or heteroalkyl group of up to 18 carbon atoms;

The polymer is of a formula selected from the group consisting of: $-[C(O)-\phi-C(O)-NH-\psi-NH]_{n_5}$ and $-[NH-\psi-NH-C(O)-\phi-C(O)]_{n_5}$, where n_5 is an integer from 2 to 100, and ϕ and ψ are divalent radicals that may be the same or different and are selected from the group consisting of $-((CH_2)_{n_6}-(CH_2CH_2O)_{n_7}-(CH_2)_{n_6})-$ and $-((CH_2)_{n_6}-(O-CH_2-CH_2)_{n_7}-(CH_2)_{n_6})-$, where n_6 is an integer from 1 to 6 and n_7 is an integer from 2-50.

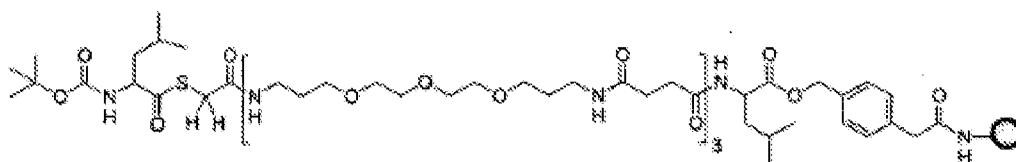
(1) Level of skill and knowledge in the art:

The level of skill to practice the art of the instantly claimed invention is high with regard to synthesis, isolation, characterization, and assays to confirm that the compound is indeed what was intended in synthesis, and has the intended function that is correlated to structure.

(2) Partial structure: (3) Physical and/or chemical properties: and (4) Functional characteristics:

The partial structures made thus far are those shown in Example 3 and Example 5 where in Example 5 the Peptide-GRFN 1852- PLP3-Leu, is made from the components of:

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with

The peptide (Y) GRFN 1852

CLSQLHSGLFLYQGLLQALEGISPELGPTLDTLQLDVADFATTIW QQMEE L-thioester

(SEQ ID NO:3) (where Cys1 is Acm protected). The physical and/or chemical

properties, from Applicant's description in the specification on page 4, and stated here:

"The invention is directed to water-soluble thioester and selenoester compounds, generators thereof, and related methods for their production and use. The subject thioester and selenoester compounds of the invention are characterized by including an amino acid synthon that is joined to a water-soluble polymer through a thioester or a selenoester. The subject thioester and selenoester compounds can be readily made using thioester and selenoester generators of the invention.

The thioester and selenoester generators of the invention comprise an amino acid synthon having an N-terminal group joined to a C-terminal group through an organic backbone, where the C-terminal group is joined to a water-soluble polymer through a thioester or selenoester moiety, and where the amino acid synthon is joined to a support through a linker that is cleavable under non-nucleophilic conditions. Cleavage generates the desired water-soluble thioester and selenoester compounds free of the support of the linker under non-nucleophilic conditions."

(5) Method of making the claimed invention:

Solid Phase peptide synthesis.

As stated supra, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that Claim 60 is a broad generic, with respect to all possible compounds encompassed by the claims. Especially Claim 60. The possible structural variations are limitless to any class of compound claimed in an extremely broad genus. There are two

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examples in the specification and while having written description for those two examples, one of which is shown supra, there is insufficient description of a common core structure that would allow one of skill in the art to practice the invention as claimed. The variables of R, R₁, R₇, and R₈, as well as the variance in n₁ and n₂ from 0 to 2, and n₃ from 0 to 100, does not allow for a core structure to inform one of ordinary skill in the art as what is to be made. The variance in the amino acid side chains for n₃ can be upwards of 100²⁰ (length of the amino acid chain raised to the number of amino acids used to make the peptide) is enormous and does not include the variance in n₂ or the inclusion of other side chains that do not correspond to the side chains of amino acids. Further, the polymer for the instant invention is also variant in structure as well, that of -C(R₇)(R₈)-U-Polymer, that there is no real common core structure for the linker-polymer. The variance in -C(R₇)(R₈)- is enormous, involving untold numbers of unrelated structures as described in genus language of substituted and unsubstituted linear or branched chain alkyl, aryl, heteroaryl and benzyl moieties. When considered with -U-, which is defined as linear or branched chain alkyl or heteroalkyl group of up to 18 carbon atoms, creates an enormous group of unrelated structures, all with different properties (aryl vs. heteroaryl vs, alkyl vs. branched alkyl, etc...). Given the enormity of the variance just within -C(R₇)(R₈)-U- portion of the claim molecule, and considered in light of what has been reduced to practice and exemplified in the specification, leaves the description of that portion of the molecule to the imagination of the skilled artisan and not to the Applicants specification for guidance and examples.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.

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See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.")

Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

(10) Response to Argument

Applicant's arguments, as found on page 5-13 of the appeal brief present, at least, eleven case law to rebut the written description rejection, but in presenting the case law, Applicant's have not presented why the case law is relevant to the instantly claimed invention. The presentation of the case law reads more of history than of applicability in the instant case. For example, *Falkner v. Inglis*, 448 F.3d 1357;79 USPQ2d 1001 (Fed. Cir. 2006), is used to argue that it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation. *Id.* It should be noted that this language is for 35 U.S.C. 112 Paragraph for Enablement and not Written Description.

Applicants continue with *Falkner v. Inglis* in describing what the issues were in the case, those of "essential genes" of the vector virus. The expert testimony stated that

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the “essential genes” were well known in the art, and that the skilled artisan would have been readily able to choose an essential poxvirus gene based on references that were publicly available. How “essential genes” of the vector virus relates to the structures of -C(R₇)(R₈)-U-, for example, is not provided by the Applicants. The structures of -C(R₇)(R₈)-U- is Applicants invention and not “essential genes” found in nature that one of ordinary skill in the art would either equate with -C(R₇)(R₈)-U-, or look up in the literature. The -C(R₇)(R₈)-U- is not found in genes or nature, and is only represented by one structure reduced to practice.

On page 7 of the Appeal Brief, and continuing with *Falkner v. Inglis*, Applicants state that examples are not necessary to support the adequacy of a written description, pointing out that the Federal Circuit stated "A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Falkner, (quoting approvingly from *LizardTech, Inc. v. Earth ResourceMapping, PTY, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005)). Thus, it is argued, that it is unnecessary to spell out every detail of the invention. Only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation. *Id.* The problem with this argument is that the structures instantly claimed, are not genes or proteins found in the prior art, but the structures made in the Formula of Claim 1, those of -C(R₇)(R₈)-U- to which known

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peptides and protein can be attached is not something that can be found in the prior art. Since the alleged novelty lies in this region, one must look to the specification and for examples to understand what the structures are that are claimed in genus language. With only three examples, one is not convinced that the Applicant was in possession of the invention at the time of filing, but rather has created a wish-list of compounds that, for U, fall under the language of U is a linker or spacer and may be present or absent and, when present, consists of a linear or branched chain alkyl or heteroalkyl group of up to 18 carbon atoms. Up to 18 carbon atoms with all the implied substitutions leaves it to the imagination and not the specification.

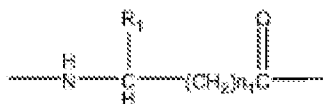

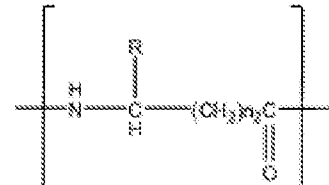
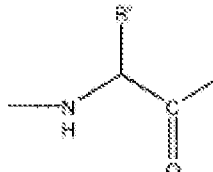
On page 7 and 8 of the Appeal Brief, *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. See also *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d are the instant invention to genes and proteins, but are not stating how they equate to the instantly claimed invention. The structures of -C(R₇)(R₈)-U-Polymer is not a gene or a protein, and is not found in nature. One of skill in the art does not look in the prior art references to determine what the structures for -C(R₇)(R₈)-U-Polymer are, and Applicants have not detailed how -C(R₇)(R₈)-U-Polymer relates to essential poxvirus genes in *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d. Again, the listing and presenting of the case law through the Appeal Brief appears to be irrelevant because Applicants are not arguing why it is relevant to what is instantly claimed. The structure of -C(R₇)(R₈)-U-Polymer is not the same as “essential genes” and proteins found in nature. The -C(R₇)(R₈)-U-Polymer moieties are not found in nature but appear to be essential to the invention, the specification is where one of ordinary

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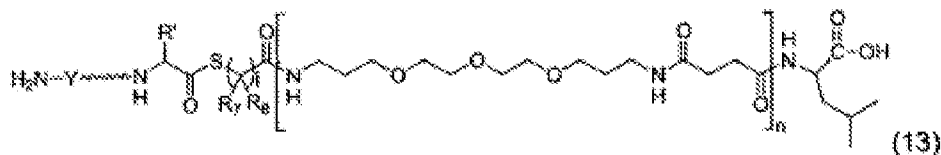
skill in the art looks to understand the meaning of these structure, and see what has been exemplified.

Applicant's arguments that logic of the rejection is misplaced and erroneous because, contrary to what is alleged in the rejection, the molecules of the invention are not described only by a functional characteristic. It is argued that *"a specific and limited core structure is provided in independent claim 60 with a reasonably limited constituents attached to that core, and the molecules are not claimed by their function at all."* Thus, it is argued *"the rejection does not find support in the facts of the present case."* In addressing this argument, it should be noted that U is given a function, that of a linker or spacer. More important, this structure considered with $-C(R_7)(R_8)-U-$ is not a limited core, but to a very large genus of unrelated structures that are attached at the point where the reaction is occurring, see the specification at page 37.

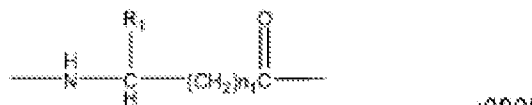
On Page 11 of the appeal brief, Applicants attempt to show that the claims and specification have adequate written description by showing a correlation between the claims and specification. There are three examples from page 11 that attempt to show that one of ordinary skill in the art would find support in the meaning of the variables of Claim 60.

Claim	Specification
Y	Y
	
	

The compound of reference in this example is

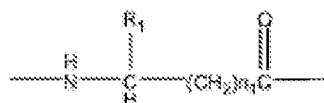


Here it can be seen that Y is Y . But,



is in the

next portion of the molecule. The plain meaning of --- is that of a bond . The



plain meaning of amino acid is that of an amino acid, a naturally occurring amino acid when $n_1 = 1$. Thus, Applicants are equating amino acids to a bond.

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It is further noted that in the next moiety example, R is R' and essentially undefined in the specification. Lastly, from the example, U is -C(O)- , and is the only example of what is claimed to be a linear or branched chain alkyl or heteroalkyl group of up to 18 carbon atoms.

In summary, the arguments presented appear to be a presentation of what has been decided in the individual case law, but the reasons for why these case laws are pertinent to the instantly claimed invention have not been addressed. It is believed that Applicants are not in possession of the claimed invention as exemplified by the specification and the rejection is, therefore, maintained.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Thomas S Heard/

Examiner, Art Unit 1654

Conferees:

/MP WOODWARD/

Primary Examiner, TC 1600



/Cecilia Tsang/

Supervisory Patent Examiner, Art Unit 1654